REMARKS

Claims 1-23, as provided by preliminary amendment mailed to the U.S. Patent and Trademark Office on February 16, 2005, are pending and were subject to a restriction requirement. In the Office Action mailed on November 17, 2008, the Examiner required restriction of the claims to one of three groups under 35 U.S.C. §121 and 372.

The Examiner restricted the claims of the present application, contending as follows:

Group I: Claims 1-12, drawn to pharmaceutical formulation comprising antibodies with specific shelf life requirements;

Group II: Claims 13-15 drawn to buffer compositions; and

Group III: Claims 16-23, drawn to pharmaceutical compositions comprising antibodies and further comprising specific buffers, surfactants, and stabilizers.

Applicants believe the Examiner meant to divide the claims as follows, based on dependencies, and respectfully request clarification:

Group I: Claims 1-12;

Group II: Claims 13-16;

Group III: Claims 17-23.

Applicants respectfully traverse the restriction of the claims and requests reconsideration and withdrawal of restriction requirement.

Proper restriction between independent and distinct inventions claimed in the same application requires that (1) the invention must be independent and distinct as claimed and (2) there must be a serious burden placed on the Examiner by not requiring election. If either criteria is not met, restriction is not proper. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed in a patent application. The term "distinct", means two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed, and are patentable over each other. (see M.P.E.P. §802.01). Further, with respect to the burden of the examination, M.P.E.P. §803 states in relevant part, "If

the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions."

Applicants assert that the claims are drawn to a single inventive concept and a single inventive effort, the search and examination of which would not place a serious burden on the Examiner. The claims are different aspects and embodiments of the same disclosed subject matter.

Applicants' invention is directed to aqueous pharmaceutical antibody formulations. In certain embodiments, these aqueous formulations contain a TNF antibody, for example, D2E7, and certain combinations of additional excipients. Contrary to the Examiner's contention regarding Group II, those claims do recite antibodies.

Therefore, the subject matter of Applicants' patent application is not "independent" as determined by M.P.E.P. 802.01 and does not meet the criteria for "distinct" as defined in M.P.E.P. § 802.01.

Furthermore, according to § 806.05 of the M.P.E.P., a "separate field of search" means, "it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists" (*emphasis added*).

The present application contains a single searchable, unifying aspect, i.e., aqueous pharmaceutical antibody formulations. Therefore, Applicants submit that the Examiner can search and examine the application without serious burden. Thus, Applicants respectfully submit that Applicants' invention does not meet the threshold of "two or more independent and distinct" inventions as required in 35 U.S.C. §121 and as such the restriction requirement is improper. In view of the foregoing, Applicants respectfully request withdrawal of the restriction requirement.

Notwithstanding Applicants' belief that the restriction requirement is improper, and without in any way acquiescing to the reasons for the requirements set forth in the Office Action,

but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group III.

Respectfully submitted,

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